

## **DETAILED ACTION**

### ***Status of the Application***

This Office Action is in response to applicant's arguments filed on 10/09/2007. Claim(s) 3-5 are pending. Claim(s) 3 and 5 have been amended. Claim(s) 5 has been added. Claim(s) 2-5 are examined herein.

### ***Response to Arguments***

For sake of compact prosecution the term "inhibition" has been interpreted to mean treatment.

Applicant's amendments have rendered the 102(b) rejection of claims 1 and 2 over Cappelli-Schellpfeffer (WO 01/70210 A2) moot and the rejection is hereby withdrawn.

Applicant's arguments with respect to the 102(b) rejection of claims 3-4 as being unpatentable over Cappelli-Schellpfeffer (WO 01/70210 A2) has been fully considered but found not persuasive. Cappelli-Schellpfeffer specifically teaches the topical application of aspirin on the surface of a scar or healed wound including keloids. Cappelli-Schellpfeffer specifically teaches that by "improving" the size and appearance of a healed wound or a scar is meant to alleviate, either partially or completely, symptoms such as pain, tingling, itching, burning, discoloration; reducing the size of a scar; reducing surface irregularities; reducing the accumulation of fibrous tissue; and/or partially or completely eliminating the scar (page 11, line 23- line 27). The reference

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provides working examples where topical application of aspirin reveals scar contracture and flattened scar contours (see examples 4 and 5).

In view of Applicant's amendments, the 102(b) rejection of the last Office Action has been maintained for reasons of record and modified below as a result of Applicant's claim amendments in addition to newly applied 112 rejections.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the treatment of keloid and/or hypertrophic scar formation and for treatment of pain and pruritus, does not reasonably provide enablement for the inhibition/prevention of of keloid and/or hypertrophic scar formation and for inhibition/prevention of pain and pruritus as recited in these claims.

The instant claims are drawn to a method for the inhibition/prevention of keloid and/or hypertrophic scar formation and for inhibition/prevention of pain and pruritus. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte*

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*Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant invention pertains to a method for the inhibition/prevention of keloid and/or hypertrophic scar formation and for inhibition/prevention of pain and pruritus.

The state of the prior art:

The skilled artisan would view that the inhibition/prevention of one or more symptoms of keloid and/or hypertrophic scar formation and for inhibition/prevention of pain and pruritus totally, absolutely, or permanently, is highly unlikely, since one cannot guarantee that the keloid and/or hypertrophic scar formation and the pain and pruritus of such will always be prevented.

The relative skill of those in the art:

The relative skill of those in the art is very high.

The predictability or lack thereof in the art:

The skilled artisan would view that the treatment to inhibit/prevent of one or more symptoms of keloid and/or hypertrophic scar formation and for inhibition/prevention of pain and pruritus, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples:

In the instant case, no working examples are presented in the specification as filed showing how to prevent inhibit/prevent of one or more symptoms of keloid and/or hypertrophic scar formation and for inhibition/prevention of pain and pruritus totally, absolutely, or permanently. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

*Genentech, Inc. v. Novo Nordisk*, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the combination in the instant claims whether inhibition/prevention of one or more symptoms of keloid and/or hypertrophic scar

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formation and for inhibition/prevention of pain and pruritus totally, absolutely, or permanently.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term, "effective amount", in the instant claims is a relative term that renders the claim indefinite. The term "effective amount" is not defined by the claim and although the specification discloses "[t]he effective amount of the drug is 0.005~80% by weight per total", one is not able to ascertain from the broad range provided, what an effective amount would be carry to forth said invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Cappelli-Schellpfeffer (WO 01/70210 A2).

Cappelli-Schellpfeffer teaches methods and compositions for improving the size and appearance of a healed wound, which may be a scar such as, a hypertrophic scar, a keloid, Dupuytren's contractures, acne scars, fibrotic scars, and reactive scars. Cappelli-Schellpfeffer teaches a method, which includes administering to an individual having a healed wound or scar a therapeutically effective amount of a cyclooxygenase inhibitor (page 2, lines 20-27). Note that acetylsalicylic acid is administered to such a patient (page 3, line 25-page 4, lines 26) and is administered topically (abstract).

Furthermore, Cappelli-Schellpfeffer teaches that by "improving" the size and appearance of a healed wound or a scar is meant to alleviate, either partially or completely, symptoms such as pain, tingling, itching, burning, discoloration; reducing the size of a scar; reducing surface irregularities; reducing the accumulation of fibrous tissue; and/or partially or completely eliminating the scar (page 11, line 23- line 27).

Additionally, Cappelli-Schellpfeffer teaches the composition is used to relieve or to prevent a condition of scar irritation, in particular in a case wherein scar irritation leads to symptoms including itching, and to a patient's self-inflicted mechanical action of scratching, which can result in further scar irritation, and possible contamination and invasion of the scar with native skin organisms (page 12, line 28-page 12, line 2), thus meeting the limitations of claims 3-5.

***Conclusion***

Claims 3-5 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

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Supervisory Patent Examiner, Art Unit 1617